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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,182	06/19/2002	William A. Banks	01017/36667	7965
4743 7590 12/26/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER KOLKER, DANIEL E	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 12/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/049,182	Applicant(s) BANKS, WILLIAM A.	
	Examiner Daniel Kolker	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-76 is/are pending in the application.
- 4a) Of the above claim(s) 6-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20071220</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The remarks and amendments filed 2 August 2007 have been entered. Claims 5 and 77 are canceled; claims 1 – 4 and 6 – 76 are pending.

Election/Restrictions

2. Claims 6 – 76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 1 March 2005.
3. Claims 1 – 4 are under examination.

Withdrawn Rejections and Objections

4. The following rejections and objections set forth in the previous office action are withdrawn:
 - A. The rejection of claims 1 – 4 under 35 USC 103(a) is withdrawn in light of the arguments which persuasively set forth the reasons why the claimed invention would not have been obvious to one of ordinary skill in the art.
 - B. The rejection of claim 5 under 35 USC 112, second paragraph is moot as the claim is now canceled.

New Rejections and Objections

Claim Objections

5. Claims 3 and 4 are objected to because of the following informalities: each claim recites the words "said leptins said leptins" in the third-to-last line. It appears that the phrase "said leptins" has mistakenly been duplicated. It is suggested that applicant either cancel one iteration of "said leptins" or alternatively provide arguments as to how the duplicated term serves to define the invention. Appropriate correction is required.

Additionally, to reflect more conventional claim language it is recommended that applicant modify the phrase "wherein the leptin is biologically active", which appears at the second-to-last line of claims 3 and 4, to read "wherein the leptin can modulate body weight", "wherein the leptin can control appetite regulation", or "wherein the leptin can modulate body weight and/or metabolism" as each of these phrases points to specific biological activities leptin

is known to have. Support for these phrases is found in the specification at p. 7 lines 20 – 21, p. 7 lines 22 – 23, and p. 3 lines 29 – 30 respectively.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it recites the term “an effective amount of exogenous leptin effective to modulate the transport of leptin across the blood brain barrier”. It is unclear how leptin modulates its own transport across the blood brain barrier (BBB). The specification discloses that epinephrine modulates leptin across the BBB, but does not indicate that leptin modulates its own transport. The skilled artisan could not determine which amounts of leptin are included or excluded by the claim, so the claim is indefinite. Claims 2 – 4 depend from this indefinite claim but do not further clarify this issue and therefore are rejected as well.

In order to overcome this rejection, it is recommended that applicant amend claim 1 part i) to read “administering to the mammal exogenous leptin; and” as this would clarify the scope of patent protection desired. While the term “exogenous leptin” is broad, the skilled artisan could determine the scope of the claim.

Conclusion

7. No claim is allowed.

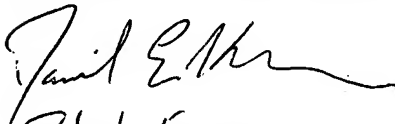
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Patent Examiner
Daniel E. Kolker, Ph.D.

December 20, 2007